

REMARKS

Claims 1-29 are pending in the present application.

Claims 1-4, 6-7, 10-14, 16-17, 20-25 and 27-29 have been rejected.

Claims 5, 8-9, 15, 18-19 and 26 have been objected to.

Claim 22 has been amended.

Claims 1-29 remain in the case.

Reconsideration of Claims 1-29, as amended, is respectfully requested.

Amendment to the Claims

Claim 22 has been amended to correct a typographical error.

The phrase “one of the step of” has been amended to read “the step of.”

Allowable Subject Matter

In Paragraph 9 on Page 8 of the July 13, 2004 Office Action, the Examiner objected to Claims 5, 8-9, 15, 18-19 and 26 as being dependent upon a rejected base claim, but stated that the claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claim. The Applicants thank the Examiner for the determination that Claims 5, 8-9, 15, 18-19 and 26 contain allowable subject matter.

Double Patenting Rejection

In Paragraph 2 on Page 2 of the July 13, 2004 Office Action, the Examiner rejected Claims 20-21 and Claims 28-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable of Claims 13, 15 and 23-25 of United States Patent No. 6,666,830 to Michael L. Lehrman et al. (hereafter “*Lehrman*”) in view of United States Patent No. 4,715,367 to Robert B. Crossley (hereafter “*Crossley*”). The Applicants respectfully traverse the Examiner’s rejection of Claims 20-21 and Claims 28-29 for obviousness-type double patenting over *Lehrman* and in view of *Crossley*. For the reasons set forth below, the Applicants respectfully request the Examiner to withdraw the obviousness-type double patenting rejection of Claims 20-21 and Claims 28-29.

The Examiner stated that “A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (c)) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application.” (July 13, 2004 Office Action, Page 2, Lines 10-13).

In the instant case there is no need to file a terminal disclaimer. The patent application (09/641,982) that issued as United States Patent No. 6,666,830 was filed on August 17, 2000. The present patent application (09/641,983) was also filed on August 17, 2000. In fact, the patent application serial numbers (09/641,982) and (09/641,983) are consecutive numbers.

United States Patent No. 6,666,830 and the present patent application have the same inventors. In addition, United States Patent No. 6,666,830 and the present patent application are commonly owned by the same corporate entity (East River Ventures, L.P. of New York, New York).

The term of a United States Patent is now set so that a patent expires twenty (20) years from the earliest referenced filing date of the patent application. No longer does a patent term expire seventeen (17) years from the issue date of the patent. Therefore, United States Patent No. 6,666,830 and any patent that results from the present patent application and will both expire twenty (20) years from August 17, 2000. There will be no post-expiration “extension” of the period of United States Patent No. 6,666,830. A terminal disclaimer is not necessary for the present patent application.

Nevertheless, the Applicants respectfully submit that a terminal disclaimer is not necessary for an additional reason. The additional reason is that Claims 20-21 and Claims 28-29 are not *prima facie* obvious over the suggested combination of United States Patent No. 6,666,830 to *Lehrman* and United States Patent No. 4,715,367 to *Crossley*.

During *ex parte* examinations of patent applications, the Patent Office bears the burden of establishing a *prima facie* case of obviousness. MPEP § 2142; *In re Fritch*, 972 F.2d 1260, 1262, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the Patent Office. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ. 785, 788 (Fed. Cir. 1984). Only when a *prima facie* case of obviousness

is established does the burden shift to the applicant to produce evidence of non-obviousness. MPEP § 2142; *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). If the Patent Office does not produce a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of a patent. *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); *In re Grabiak*, 769 F.2d 729, 733, 226 USPQ 870, 873 (Fed. Cir. 1985).

A *prima facie* case of obviousness is established when the teachings of the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art. *In re Bell*, 991 F.2d 781, 783, 26 USPQ2d 1529, 1531 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed invention and the reasonable expectation of success must both be found in the prior art, and not be based on an applicant's disclosure. MPEP § 2142.

Applicants respectfully submit that the Patent Office has not established a *prima facie* case of obviousness with respect to Claims 20-21 and Claims 28-29 of the Applicants' invention. The Examiner stated that “[United States Patent Number 6,666,830] discloses at least an apparatus

for terminating a physiological process that causes partially occluded breathing to occur in an airway of a person due to partial obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing occurs, . . .”

(Emphasis added) (July 13, 2004 Office Action, Page 2, Line 20 to Page 3, Line 1).

Applicants respectfully traverse this characterization of the *Lehrman* reference. Claim 13 of *Lehrman* is directed to “An apparatus for detecting the onset of an obstructive sleep apnea event before cessation of breathing occurs, . . .” (Emphasis added). Similarly, Claim 15 and Claims 23-25 of *Lehrman* are directed to “A method for detecting the onset of an obstructive sleep apnea event before cessation of breathing occurs, . . .” (Emphasis added). Claims 13, 15 and 23-25 are directed to detecting (and not terminating) an onset of a sleep apnea event.

In considering an earlier patent in a double patenting analysis only the claims of the earlier patent may be used. That is, the patent disclosure of the specification may not be used as prior art.

Double patenting is concerned with attempts to *claim* the same or related subject matter twice. Thus, the standard for comparison for the second patent is what was claimed in the first patent, not what was disclosed in the specification of the first patent. E.g., Reynolds Metals Co. V. Continental Group, Inc., 525 F.Supp. 950, 972, 210 USPQ2d 911, 929 (N.D. Ill. 1981)(“To establish double patenting between two patents issued to the same inventor at different times, only the claims are compared . . .”). (Emphasis in original). *Chisum on Patents*, § 9.03[1][a], Volume 3, p. 9-15, 2003.

It is clear that Claims 13, 15 and 23-25 of *Lehrman* do not refer to terminating an onset of a sleep apnea event. Instead they refer only to the detection of an onset of a sleep apnea event. This is a significant distinction.

The Examiner stated that “[United States Patent Number 6,666,830] also discloses at least a method for terminating a physiological process that causes partially occluded breathing to occur in an airway of a person due to partial obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing occurs, . . .” (Emphasis added) (July 13, 2004 Office Action, Page 3, Lines 8-11).

The Applicants also respectfully traverse this characterization of the *Lehrman* reference. As previously noted, Claim 15 and Claims 23-25 of *Lehrman* are directed to “A method for detecting the onset of an obstructive sleep apnea event before cessation of breathing occurs, . . .” (Emphasis added). Claims 13, 15 and 23-25 are directed to a method of detecting (and not to a method of terminating) an onset of a sleep apnea event. Because the *Lehrman* reference does not claim an apparatus or method for terminating an onset of a sleep apnea event, it is not a properly cited reference in the Examiner’s double patenting analysis.

The Examiner also stated that “[United States Patent Number 6,666,830] does not specify that the apparatus or method include generating and alarm stimulating the person’s neck to terminate the partially occluded breathing.” (July 13, 2004 Office Action, Page 4, Lines 2-4). The Applicants agree that the *Lehrman* reference does not claim terminating an onset of a sleep apnea event.

The Examiner stated that “Crossley discloses an apparatus and method for terminating partially occluded breathing caused by a sleep apnea event that involves sensing the onset of a sleep apnea event and generating an alarm signal in the form of a stimulus applied to the person’s neck,

to terminate the event.” (July 13, 2004 Office Action, Page 4, Lines 5-8). The Applicants respectfully traverse this characterization of the *Crossley* reference.

Crossley discloses and claims a multifunctional behavioral modification device that creates and delivers a regulatable aversive shock to a motor nerve in the neck of a person in order to train the person to subconsciously change his or her behavior in response to the aversive shock. Unlike the Applicants’ invention, *Crossley* is not able to detect a sleep apnea event before cessation of breathing occurs. That is, *Crossley* can only detect instances when breathing has already stopped.

For example, Claim 1 of *Crossley* claims “means for detecting breathing indicating that breathing has stopped.” (Emphasis added). *Crossley* generates a pulsating electrical shock “when breathing stops” and continues the shock “until breathing re-starts.” (*Crossley*, Column 3, Lines 24-26). “Treatment consists of regulatable aversive shock . . . pulsatingly administered from sleep apnea until breathing restarts.” (Emphasis added) (*Crossley*, Abstract). These portions of *Crossley* make it very clear that *Crossley* only detects the absence of breathing. Unlike the Applicants’ invention, *Crossley* is not able to anticipate or detect a sleep apnea event before breathing stops. This is a significant distinction.

In the Applicant’s invention an onset of a sleep apnea event is detected before breathing stops. Then a stimulus is created and applied to the person’s neck muscles to cause the person to

immediately move the person's head backwards to terminate the onset of the sleep apnea event before breathing stops.

Unlike the method employed by *Crossley*, the Applicants' method does not have to "condition the subconscious mind" over an extended period of time. *Crossley* states that "The subconscious mind associates the "punishment" of slight electrical shock with a snore sound and after a few night's use, the user becomes conditioned (behavior modification) to stop snoring." (Emphasis added) (*Crossley*, Column 1, Lines 30-36). *Crossley* applies the same aversive shock therapy technique (behavioral modification) to snoring, bruxism, and apnea. (*Crossley*, Abstract). *Crossley* states that "It is the object of this invention to use conditioning of the sub conscious mind to condition against or effectively treat both types of apnea." (*Crossley*, Column 2, Lines 2-5). Furthermore, the behavior modification technique of *Crossley* must be periodically repeated because the *Crossley* conditioning does not last. (*Crossley*, Column 1, Lines 33-36).

Also significant is the fact that the shock electrodes 8 of *Crossley* are applied to the front of the neck of the person. Figure 3 of *Crossley* shows that the shock electrodes 8 are located on the bottom of the *Crossley* collar unit. The top of the *Crossley* collar unit is shown in Figure 2. When the *Crossley* collar unit is fastened in place (as shown in Figure 1 of *Crossley*) the shock electrodes 8 are located on the front of the neck. Specifically, one of the shock electrodes 8 is located under the snore detector microphone bypass switch 6 and the other shock electrode 8 is

located under the bruxism sensor plug-in port 3. Therefore, the *Crossley* collar is structurally incapable of providing a stimulus to the back of the neck that would cause a person to move his or her neck backwards. It is clear from this fact alone that the *Crossley* collar is incapable of performing the method of the Applicants' invention.

The Examiner stated that "It would have been obvious to one skilled in the art at the time the invention was made to have provided the apparatus and method disclosed by [United States Patent No. 6,666,830], wherein the apparatus and method stimulate the person's neck, as taught by Crossley, to terminate the apnea event." (July 13, 2004 Office Action, Page 4, Lines 9-11). The Applicants respectfully traverse this assertion of the Examiner.

As previously mentioned, the patent disclosure of United States Patent No. 6,666,830 is not prior art with respect to the present application. As also previously mentioned, the patent application that subsequently issued as United States Patent No. 6,666,830 and the present patent application were both filed on the same day.

There is nothing in the claims of United States Patent No. 6,666,830 that refers to terminating an onset of a sleep apnea event. There is nothing in the *Crossley* reference that refers to terminating an onset of a sleep apnea event before the cessation of breathing. There is nothing in the *Crossley* reference that refers to the concept of creating a stimulus to the neck muscles of a person to cause the person to move his or her head backwards to extend the neck and open the person's airway.

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine claims of the *Lehrman* reference (i.e., U.S. Patent No. 6,666,830) and the *Crossley* reference. “When a rejection depends on a combination of prior art references, there must be some teaching, or motivation to combine the references.” *In re Rouffet*, 149 F.3d 1350, 1355-56, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). “It is insufficient to establish obviousness that the separate elements of an invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the references.” *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997). The Applicants respectfully submit that there exists no teaching, suggestion or motivation in the prior art to combine the teachings of the *Lehrman* reference and the teachings of the *Crossley* reference.

The Examiner stated that the supposed motivation was “to terminate the apnea event.” (July 13, 2004, Page 4, Line 11). This supposed motivation is too vague and indefinite to serve as a legally sufficient motivation to combine the references. This is especially so because the method used by *Crossley* to “terminate the apnea event” is significantly different than the method used by the Applicants. The broad concept of “termination of an apnea event” is really a general statement of the problem and is not a specific suggestion or motivation to combine references.

When two references are combined the combination of the references must teach or suggest all the claim limitations. In the present case, even if the *Lehrman* reference were combined with the *Crossley* reference, the combination of the *Lehrman* reference and the *Crossley* reference would not

teach, suggest or even hint at the Applicants' invention. This is because, as previously described, the *Crossley* reference does not teach, suggest, or even hint at the Applicants' concept of detecting and terminating an onset of an obstructive apnea event before the cessation of breathing occurs. The *Crossley* reference also does not teach, suggest, or even hint at the Applicants' concept of terminating an onset of an obstructive apnea event by creating a stimulus to the neck muscles of a person to cause the person to move his or her head backwards to extend the neck and open the person's airway before the cessation of breathing occurs.

The Applicants therefore respectfully request the Examiner to withdraw the nonstatutory double patenting rejections of Claims 20-21 and Claims 28-29 in view of the Applicants' remarks concerning the *Lehrman* reference and the *Crossley* reference.

35 U.S.C. § 103(a) Obviousness

In Paragraph 4 on Page 4 of the July 13, 2004 Office Action, the Examiner rejected Claims 1, 2, 6-7, 10-12, 16-17, 20-22, 25 and 27 under 35 U.S.C. § 103 (a) as being obvious over United States Patent No. 5,123,425 to John L. Shannon, Jr. et al. (hereafter "Shannon") in view of United States Patent No. 4,715,367 to Robert B. Crossley (hereafter "Crossley").

In Paragraph 5 on Page 6 of the July 13, 2004 Office Action, the Examiner also rejected Claims 3-4, 13-14 and 23-24 under 35 U.S.C. § 103 (a) as being unpatentable over

Shannon in view of *Crossley* and further in view of United States Patent No. 6,652,566 to Scott A. Lambert (hereafter “*Lambert*”).

The Applicants respectfully traverse (1) the Examiner’s rejection of Claims 1- 2, Claims 6-7, Claims 10-12, Claims 16-17, Claims 20-22, Claim 25 and Claim 27 as being obvious in view of *Shannon* and *Crossley*, and (2) the Examiner’s rejection of Claims 3-4, Claims 13-14 and Claims 23-24 as being obvious in view of *Shannon* and *Crossley* and *Lambert*. The Applicants respectfully request the Examiner to withdraw the rejections of the above referenced claims in view of the Applicants’ remarks concerning the prior art references.

A. Rejection of Claims 1-2, 6-7, 10-12, 16-17, 20-22, 25 and 27

The Applicants hereby repeat and incorporate by reference all of the statements and arguments previously made with respect to the *Lehrman* reference and the *Crossley* reference in connection with the Applicants’ traversal of the Examiner’s double patenting rejections.

The Examiner stated “Shannon, Jr. et al disclose an apparatus for terminating a physiological process (sleep apnea) that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before complete cessation of breathing occurs, wherein the apparatus comprises: at least one microphone (24) capable of being acoustically associated with said person, said microphone capable of detecting breathing sounds within said airway of said person and capable of generating signals representative of said breathing sounds. The microphone detects the

presence of breath OR it detects snoring sounds, and generates and electrical signal representative of such (see column 3, lines 25-30 and column 4, lines 19-42). Shannon, Jr. et al. also specifies that instead of a microphone an air flow sensor can be utilized to obtain information concerning the breathing of a person. Shannon, Jr. et al. disclose a controller (20) coupled to the microphone and capable of receiving said signals. A filter (204) is coupled between the microphone and the controller, wherein the filter is capable of filtering said signals from the microphone to create filtered signal representative of said breathing or snoring sounds. The controller is capable of identifying within the filtered signals at least one signal pattern (a pattern of said snoring sounds) that is associated with a breathing pattern of said person that occurs at the onset of said physiological process (as evidenced by Crossley, which discloses a link between snoring sounds and the onset of an apnea event), before cessation of breathing occurs, and is capable of generating an alarm signal in response thereto. A stimulus generator (26, 28) is coupled to the controller, the stimulus generator being capable of receiving said alarm signal from said controller, and in response thereto, creating an electrical current stimulus that is applied to said person to terminate said physiological process before cessation of breathing occurs. The controller of the apparatus is further structurally capable of operating only during one half of the respiration cycle, or for whatever portion of the respiration cycle it is desired by the user to have functional operation. Shannon, Jr. et al. do not specify that the stimulus created by the stimulus generator be applied to the person's neck muscles.” (July 13, 2004 Office Action, Page 4, Line 23 to Page 6, Line 2).

The Applicants respectfully traverse the Examiner's assertion that the *Shannon* reference discloses an apparatus for terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete obstruction of said airway due to an obstructive sleep apnea event, wherein said physiological process is terminated before cessation of breathing occurs. The *Shannon* reference does not disclose these features. Cessation of breathing must occur before the *Shannon* apparatus can detect the presence of an obstructive sleep apnea event.

The Applicants also respectfully traverse the Examiner's assertion that the *Shannon* apparatus is capable of identifying "at least one signal pattern (a pattern of said snoring sounds) that is associated with a breathing pattern of said person that occurs at the onset of said physiological process (as evidenced by Crossley, which discloses a link between snoring sounds and the onset of an apnea event), before cessation of breathing occurs, and is capable of generating an alarm signal in response thereto." Snoring is not a physiological process that causes cessation of breathing to occur in an airway of a person. Many people snore and never have obstructive sleep apnea. The Examiner suggested that *Crossley* discloses a "link" between snoring and the onset of obstructive sleep apnea. But a strict correlation between snoring and obstructive sleep apnea does not exist. Some people have obstructive sleep apnea and do not snore. Therefore, the detection of snoring and the detection of obstructive sleep apnea are two different independent processes. The detection of snoring does not always mean that obstructive sleep apnea will occur or that obstructive sleep apnea will be detected. The *Shannon* apparatus can detect snoring before cessation of breathing occurs

(because snoring is breathing) but the *Shannon* apparatus can not detect obstructive sleep apnea before cessation of breathing occurs.

The Applicants' invention is capable of identifying the "onset" (i.e., the beginning) of an obstructive sleep apnea event before the obstructive sleep apnea event (i.e., cessation of breathing) actually occurs. The *Shannon* apparatus is not able to do this. Cessation of breathing must occur before the *Shannon* apparatus can detect the presence of an obstructive sleep apnea event. There is nothing in *Shannon* that suggests or even hints at the detection of a breathing pattern that occurs at the onset of an obstructive sleep apnea event before cessation of breathing occurs.

The Applicants' invention terminates a physiological process that causes cessation of breathing due to an obstructive sleep apnea event before cessation of breathing occurs by (1) detecting breathing sounds within an airway of a person, and (2) generating signals that are representative of the breathing sounds, and (3) identifying within the signals at least one signal pattern that is associated with a breathing pattern of the person that occurs at the onset of the physiological process before cessation of breathing occurs, and (4) applying a stimulus to the neck muscles of a person to cause the person to move the neck muscles to cause the person's head to move backwards to restore normal breathing before cessation of breathing occurs.

The *Shannon* apparatus does not teach the concept of detecting the onset of an obstructive sleep apnea event before cessation of breathing occurs. The *Shannon* apparatus also does not teach the concept of stimulating the neck muscles of a person to restore normal breathing before cessation

of breathing occurs. Therefore, the Applicants respectfully submit that the claims of the patent application are not obvious in view of the *Shannon* reference.

The *Shannon* reference shows that the electrodes 26 and 28 are located at the front of collar 10. (*Shannon*, Figures 1, 4, 5). Electrodes 26 and 28 are each “fixed to main substrate 12 such that it will be properly located to stimulate the genioglossus and related muscle groups when collar 10 is in position.” (*Shannon*, Column 3, Lines 43-48). In contrast, the electrodes 500d of the present invention are located at the back of collar 145 where they are placed adjacent to the neck muscles of the person who is wearing collar 145. (Specification, Figure 5). This is because *Shannon* is attempting to stimulate the genioglossus (and the very small muscles that control the tongue) that are located in front of the vertebrae of the neck. The present invention is attempting to stimulate the large skeletal muscles in the neck behind the vertebrae of the neck.

The genioglossus is the muscle of the tongue. To open an occluded pharyngeal airway it is desirable to cause the tongue to extend forward. However, the tongue is only one contributor to an airway closure and other tissues unrelated to the tongue may also contribute to airway closure. The classic first step of Cardio-Pulmonary Resuscitation (CPR) is to tip up the chin of a victim in respiratory arrest to mechanically flex the head backwards. This action results in the physical defeat of the forces of surface tension that cause adhesion between the tongue and the tissue at the back of the pharynx.

Insertion of a tube that stents the airway open, or forceful tipping of the head backwards are the only certain ways to open the airway. Pulsing electrical energy transcutaneously through the tissues in the front of the neck does not assure airway opening. In fact, electrically stimulating the afferent nerves that control the tongue might actually cause the tongue to retract and thus further block the airway.

Grays Anatomy describes the genioglossus and its four related muscles. These five muscles are referred to as the Lingual Region muscles. (*Grays Anatomy*, Centennial Edition, Bounty Books, New York, 1977, pp. 323 et seq.). These muscles are related because they share one point of common attachment. The genioglossus is also known as the genio-hyo-glossus because it attaches to the jaw, the hyoid bone, and the tongue. Figure 204 on Page 323 shows clearly that these muscles are located at the anterior (front) of the neck and that they have no effect on the vertebrae of the neck. That is, they do not pull the head backwards and they do not contribute to the airway opening function which is related to the backward movement of the head. The cited portions of *Grays Anatomy* were previously submitted with the April 12, 2004 Amendment.

The neck muscles that control the backward movement of the head as opposed to the movement of the tongue are massive. They are arranged in a thick sheath that is posterior (behind) the cervical vertebrae. (*Grays Anatomy*, Figure 201 on Page 316; Figure 202 on Page 318). The cited portions of *Grays Anatomy* were previously submitted with the April 12, 2004 Amendment. The *Shannon* apparatus is trying to move the tongue. The Applicants' apparatus is

trying to move the head backwards by stimulating the large skeletal neck muscles that run up from the shoulder.

The electrodes 26 and 28 of *Shannon* are located on the neck anterior to (in front of) the cervical vertebrae. The electrodes 26 and 28 of *Shannon* are located at a significant distance from the muscles that run up the back of the neck. The skeletal muscles that control head movement that are closest to the electrodes 26 and 28 of *Shannon* are the rectus capitis group. The muscles in the rectus capitis group have upper points of attachment that are anterior to (in front of) the cervical vertebrae and, if electrically stimulated, would pull the head forward closing the airway.

With regard to the meaning of the language used in the *Shannon* reference it is clear that *Shannon* uses the word “onset” to mean the beginning of an actual apnea event when breathing ceases. For example, the output of the *Shannon* sensor “is conditioned and interpreted, and used to determine whenever an apnea event is initiated.” (*Shannon*, Column 2, Lines 42-44) (Emphasis added). That an “apnea event” requires the “cessation of breathing” may be seen from the language of Claim 1 of *Shannon*: “An apparatus for treating obstruction of an upper air passageway of a patient” (Emphasis added).

The *Shannon* reference does not disclose the concept of detecting the onset of an apnea event before cessation of breathing occurs. Like a number of prior art systems *Shannon* is capable of detecting an apnea event by determining the presence or absence of breathing. *Shannon* does not indicate the existence of an apnea event if breathing is present. “Sensor 24 is used to determine the

onset of an apnea episode. In the preferred embodiment, this is a microphone or motion sensor which generates an electrical signal corresponding to the presence of breath or snoring sounds.” (Emphasis added) (*Shannon*, Column 3, Lines 25-29). The electronic circuit 200 of *Shannon* activates a stimulation signal (using on-time timer 208, ramp generator 209 and pulse generator 210) when sensor 24 no longer detects any “presence of breath or snoring sounds.” This shows that in *Shannon* the onset of an apnea event begins when cessation of breathing occurs. *Shannon* does not analyze breath sounds that are associated with an onset of an apnea event before cessation of breathing occurs. *Shannon* does not detect a signal that indicates that an apnea event will occur.

In the Applicants’s Amendment dated January 13, 2003, the Applicants pointed out that the *Shannon* reference comprises an electronic circuit 200 that activated a stimulation signal (using on-time timer 208, ramp generator 209 and pulse generator 210) when sensor 24 no longer detects any “presence of breath or snoring sounds.” *Shannon* sends a signal to an integrator 206 to create a “level representing the integrated sensor signal.” (*Shannon*, Column 4, Lines 35-36). This “level” is compared to a threshold value set by threshold adjust 216. “This ensures that whenever the integrated circuit levels exceeds the threshold set by threshold adjust 215, a signal is set to on-time timer 208 which initiates a ramp generator 209 for the duration as set by trigger adjust 212.” (*Shannon*, Column 4, Lines 38-42). The “levels” that are created and compared to a preset threshold value in the *Shannon* device are not equivalent to the signal patterns that are generated and used in the Applicants’ invention.

This description of the *Shannon* electronic circuit 200 shows that (1) the *Shannon* device is structurally different from the Applicants' invention, and (2) the *Shannon* device is not capable of performing the functions of the Applicant's invention. *Shannon* does not disclose how the threshold adjust 216 obtains a value of threshold. There is nothing in *Shannon* that teaches or suggests that the *Shannon* threshold is anything other than a "breathing" versus "not breathing" threshold. The Applicants respectfully submit that it is not possible to use the *Shannon* device to perform the functions of the Applicants' invention. If the airway of a person was partially occluded, the threshold detection circuit of the *Shannon* device could not detect the partial occlusion.

Claim 1 of the patent application claims a controller that is capable of identifying "at least one signal pattern" that is associated with a breathing pattern of a person that occurs at the onset of a physiological process that, unless terminated, causes cessation of breathing to occur due to an obstructive sleep apnea event. The *Shannon* device is not capable of identifying such signal patterns. The *Shannon* device does not have any hardware that has the capability of the controller of the Applicants' invention.

The portions of the *Shannon* reference cited above make it clear that *Shannon* is only capable of detecting cessation of breathing. There are no portions of *Shannon* that suggest otherwise. *Shannon* does not detect and is not capable of detecting a partial obstruction of a person's airway.

The Examiner stated that "Shannon, Jr. et al. do not specify that the stimulus created by the stimulus generator be applied to the person's neck muscles." (July 13, 2004 Office Action, Page 6,

Lines 1-2). The Examiner suggested that this deficiency could be supplied by the *Crossley* reference. The Examiner stated that “Crossley discloses an apparatus for terminating a sleep apnea event that comprises a microphone that detects breathing and snoring sounds. The apparatus includes a stimulus generator that applies a stimulus to the patient’s motor nerve in the neck, upon detection of a sleep apnea event, such stimulus being capable of causing the patient’s neck muscles to move the patient’s head back and terminate the apnea event.” (July 13, 2004 Office Action, Page 6, Lines 3-7). The Applicants respectfully traverse this assertion of the Examiner.

For the reasons previously set forth, the *Crossley* apparatus is not able to anticipate or detect a sleep apnea event before the cessation of breathing occurs. Therefore, the *Crossley* apparatus is not able to remedy this particular deficiency of the *Shannon* reference. Furthermore, as previously noted, in the Applicant’s invention an onset of a sleep apnea event is detected before breathing stops. Then a stimulus is created and applied to the person’s neck muscles to cause the person to immediately move the person’s head backwards to terminate the onset of the sleep apnea event before breathing stops.

For the reasons previously set forth, it is clear that the *Crossley* apparatus does not employ a stimulus to cause “the patient’s neck muscles to move the patient’s head back and terminate the apnea event.” This concept originates in the Applicant’s patent application. The *Crossley* method employs a multifunctional behavioral modification device that creates and delivers a regulatable aversive shock to a motor nerve in the neck of a person in order to train the person over an extended

period of time to subconsciously change his or her behavior in response to the aversive shock. There is nothing in the *Crossley* reference that discloses the concept of providing a stimulus to cause a person to move his or head backward to terminate an onset of an obstructive apnea event before the cessation of breathing occurs.

The Examiner stated that “It would have been obvious to one skilled in the art at the time the invention was made to have provided the apparatus and method disclosed by Shannon, Jr. et al., wherein the stimulus created by the stimulus generator is applied to the patient’s neck, as taught by Crossley, to terminate the apnea event. The method claimed is made obvious by the normal use of the apparatus as disclosed by Shannon, Jr. et al. in view of Crossley.” (July 13, 2004 Office Action, Page 6, Lines 8-12). The Applicants respectfully traverse this assertion of the Examiner.

There is nothing in the *Shannon* reference that refers to terminating an onset of a sleep apnea event before the cessation of breathing occurs. There is nothing in the *Crossley* reference that refers to terminating an onset of a sleep apnea event before the cessation of breathing occurs. There is nothing in the *Crossley* reference that refers to the concept of creating a stimulus to the neck muscles of a person to cause the person to move his or her head backwards to extend the neck and open the person’s airway.

Under the applicable patent law, there must be some teaching, suggestion or motivation to combine the *Shannon* reference and the *Crossley* reference. “When a rejection depends on a combination of prior art references, there must be some teaching, or motivation to combine the

references.” *In re Rouffet*, 149 F.3d 1350, 1355-56, 47 USPQ2d 1453, 1456 (Fed. Cir. 1998). “It is insufficient to establish obviousness that the separate elements of an invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the references.” *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997). The Applicants respectfully submit that there exists no teaching, suggestion or motivation in the prior art to combine the teachings of the *Shannon* reference and the teachings of the *Crossley* reference.

The Examiner stated that the supposed motivation was “to terminate the apnea event.” (July 13, 2004, Page 6, Lines 10- 11). This supposed motivation is too vague and indefinite to serve as a legally sufficient motivation to combine the references. This is especially so because the method used by *Crossley* to “terminate the apnea event” is significantly different than the method used by the Applicants. The broad concept of “termination of an apnea event” is really a general statement of the problem and is not a specific suggestion or motivation to combine references.

The Examiner also stated that “The method claimed is made obvious by the normal use of the apparatus as disclosed by Shannon, Jr. et al in view of Crossley.” (July 13, 2004 Office Action, Page 6, Lines 11-12). The Applicants respectfully traverse this statement of the Examiner. For the reasons set forth above, (1) the Applicants’ method is not made obvious by the “normal use” of the *Shannon* apparatus, and (2) combining the teachings of the *Crossley* reference with the teachings of the *Shannon* reference does not remedy the deficiencies of the *Shannon* apparatus.

When two references are combined the combination of the references must teach or suggest all the claim limitations. In the present case, even if the *Shannon* reference were combined with the *Crossley* reference, the combination of the *Shannon* reference and the *Crossley* reference would not teach, suggest or even hint at the Applicants' invention. This is because, as previously described, the *Crossley* reference does not teach, suggest, or even hint at the Applicants' concept of detecting and terminating an onset of an obstructive apnea event before the cessation of breathing occurs. The *Crossley* reference also does not teach, suggest, or even hint at the Applicants' concept of terminating an onset of an obstructive apnea event by creating a stimulus to the neck muscles of a person to cause the person to move his or her head backwards to extend the neck and open the person's airway before the cessation of breathing occurs.

For the reasons set forth above, the Applicants respectfully submit that Claims 1-2, 6-7, 10-12, 16-17, 20-22, 25 and 27 contains unique and novel limitations and the claims are not obvious in view of the *Shannon* reference or the *Crossley* reference, or the two references taken in combination.

The Applicants respectfully request that the rejection of Claims 1-2, 6-7, 10-12, 16-17, 20-22, 25 and 27 under 35 U.S.C. §103(a) as being obvious over the *Shannon* reference in view of the *Crossley* reference be withdrawn and that the claims be passed to issue.

B. Rejection of Claims 3-4, 13-14 and 23-24

The Applicants hereby repeat and incorporate by reference all of the statements and arguments previously made with respect to the *Lehrman* reference and the *Shannon* reference and the *Crossley* reference in connection with the Applicants' traversal of the Examiner's previous rejections.

In Paragraph 5 on Page 6 of the July 13, 2004 Office Action, the Examiner further rejected Claims 3-4, 13-14 and 23-24 under 35 U.S.C. § 103(a) as being unpatentable over *Shannon* in view of *Crossley* and further in view of *Lambert*. The Applicants respectfully traverse the Examiner's rejections and respectfully request the Examiner to withdraw the rejections of the above referenced claims in view of the Applicants' remarks concerning the prior art references. The Applicants respectfully submit that the Patent Office has not established a *prima facie* case of obviousness with respect to Claims 3-4, 13-14 and 23-24 of the Applicants' invention.

The Applicants hereby reiterate the arguments that the Applicants have previously made with respect to the *Shannon* reference and with respect to the *Crossley* reference. There is no teaching, suggestion or even a hint in the *Shannon* reference or in the *Crossley* reference concerning the Applicants' novel and unique concepts of (1) creating a stimulus to a person's neck muscles to cause the person to move his or her neck muscles to move his or her head backwards to terminate the physiological process before cessation of breathing occurs, and (2) terminating a physiological process that causes cessation of breathing to occur in an airway of a person due to a complete

obstruction of the airway due to an obstructive sleep apnea event, wherein the physiological process is terminated before cessation of breathing occurs. A teaching or suggestion to make the Applicants' invention and a reasonable expectation of success is not found in the *Shannon* reference or in the *Crossley* reference (or in any other prior art reference). Therefore, the Applicants' invention is not *prima facie* obvious in view of the *Shannon* reference or in view of the *Crossley* reference.

The Examiner has stated that "Shannon, Jr. et al in view of Crossley disclose the previously described apparatus for terminating a sleep apnea event comprising a stimulus generator that applies a stimulus to a person's neck, to terminate a sleep apnea event. Shannon et al. in view of Crossley does not specify that the stimulus be vibratory or audible. Lambert discloses an alarm generator that produces a vibratory or audible stimulus (24) to ensure that the user is stimulated. The references are analogous since they are from the same field of endeavor, the medical monitoring arts." (July 13, 2004 Office Action, Page 6, Lines 16-22).

The Examiner then stated that "It would have been obvious to one skilled in the art at the time the invention was made to have provided the apparatus disclosed by Shannon, Jr. et al. In view of Crossley, with the vibratory or audible alarm, as taught by Lambert, to provide alternate or additional alarm systems, insuring that the user is stimulated. (July 13, 2004 Office Action, Page 7, Lines 1-4)." The Applicants respectfully traverse the Examiner's assertions and conclusions.

Lambert discloses an alarm system that utilizes a primary audible alarm 24, a secondary alarm 26, and a visual indicator 32, and a controller 34 for operating the various alarm systems.

There is no teaching or suggestion in *Lambert* to combine the *Lambert* alarm system with either the *Shannon* reference or with the *Crossley* reference or with a combination of *Shannon* and *Crossley*.

Further, the reliability that is provided by the redundant alarm system of *Lambert* is not needed for the Applicants' invention. *Lambert* states that "Reliability is a critical requirement for effective alarm systems. For example, in a hospital, a patient's life often depends on the effective operation of a medical monitor alarm." (*Lambert*, Column 1, Lines 1-13). The Applicants' invention is not a life saving monitor because people do not die from an episode of obstructive apnea. They always re-open an obstructed airway with the body's gasping reflex. Therefore, the level of reliability provided by the *Lambert* system is not required.

The Applicants respectfully traverse the Examiner's assertion that *Shannon* and *Crossley* and *Lambert* substantially disclose the Applicants' invention as claimed in Claims 3-4, 13-14 and 23-24. For the reasons previously set forth, even if the three references (*Shannon*, *Crossley* and *Lambert*) were combined, the combination would not teach, suggest or even hint at the unique and novel elements of the Applicants' invention. Therefore, the Applicants respectfully request the Examiner to withdraw the obviousness rejections of the Claims 3-4, 13-14 and 23-24 in view of the Applicants' remarks concerning the prior art references.

The Applicants respectfully submit that Claims 1-29, as amended, are all patentable over the *Shannon* and the *Crossley* reference and the *Lambert* reference whether taken individually or in

combination. The Applicants respectfully request that the rejection of Claims 1-29, as amended, be withdrawn and that Claims 1-29, as amended, be passed to issue.

The Applicants deny any statement, position or averment of the Examiner that is not specifically addressed by the foregoing argument and response. The Applicants reserve the right to submit further arguments in support of their above stated position as well as the right to introduce relevant secondary considerations including long-felt but unresolved needs in the industry, failed attempts by others to invent the invention, and the like, should that become necessary.

SUMMARY

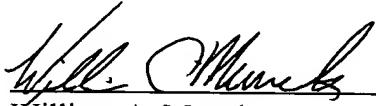
For the reasons given above, the Applicants respectfully request reconsideration and allowance of pending claims and that this Application be passed to issue. If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this Application, the Applicants respectfully invite the Examiner to contact the undersigned at the telephone number indicated below or at wmunck@davismunck.com.

The Commissioner is hereby authorized to charge any additional fees connected with this communication or credit any overpayment to Davis Munck Deposit Account No. 50-0208.

Respectfully submitted,

DAVIS MUNCK, P.C.

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William A. Munck
Registration No. 39,308

P.O. Drawer 800889
Dallas, Texas 75380
Phone: (972) 628-3600
Fax: (972) 628-3616
E-mail: wmunck@davismunck.com